

REMARKS

Reconsideration of the present application is respectfully requested for the reasons that follow. In response to this Office Action, claim 12 has been amended and claim 17 has been canceled.

Rejections under 35 USC § 102(b)

Claims 12, 13 and 15-22 are rejected under 35 USC § 102(b) as being anticipated by Van Leuven. The amendment to independent claim 12 overcomes this rejection for the reasons that follow.

The Examiner asserts that Van Leuven teaches a composition useful for treating herpes virus, condyloma, and for preventing *Staphylococcus aureus* infection and a method in which the composition is applied to the vaginal tissue of a baby's mother as a lubricant and thereafter delivering a baby. Furthermore, the Examiner argues that the Van Leuven composition does not contain any alkali metal salts of metaphosphates, and that the lubricating composition can be in the form of a liquid solution or a gel.

Van Leuven discloses a liquid biocidal composition comprising dodecyl benzene sulfonic acid or a water soluble salt thereof, lauryl diethanolamide, triethanolamine, propylene glycol, glycerine, sodium polypectate, silver ions, ammonium hydroxide and a balance of distilled water. The composition exhibits a pH in the range of from about 7.2 to about 7.8 and can be used, inter alia, as a lubricant for manual examination during labor and for assistance during delivery.

In contrast to the Examiner's view, Van Leuven, however, does not disclose a composition which is in the form of a gel. As can be derived from column 2, lines 5-8, column 6, lines 9-11 and claim 1, Van Leuven teaches the used of a liquid composition only. Turning to column 3, line 62 to column 4, line

2, the liquid composition contains an amount of between 100 to about 40 ppm by weight of sodium polypectate, which range in combination with other ingredients in the composition provides a viscosity suitable for the intended purpose. On the other hand, it is explained in column 2, lines 52-54 of Van Leuven that a 2% solution of sodium polypectate in water is so viscous that it is nearly a gel at ordinary temperatures. In view of Van Leuven disclosing a composition containing an amount of sodium polypectate of far below 2% by weight, the composition is not a gel, but must be present in the form of a liquid.

Moreover, the biocidal composition is described as requiring a pH in the range of from about 7.2 to about 7.8, which range is important or ensuring stability of the composition over a prolonged period of time and for maintaining the effective biocidal action of the composition (cf. column 6, lines 9-15). Since the polypectate only gels at a pH of less than 7 (cf. column 6, lines 15-16), it also becomes clear from this text passage that the biocidal composition according to Van Leuven is provided in the form of a liquid.

Furthermore, claim 1 of Van Leuven is directed to a method for treating external tissue of the human body, with claim 4 specifying the method to comprise applying the liquid biocidal composition to vaginal tissue of the mother prior to delivery. In contrast, the method according to the present invention requires the composition to be introduced into the birth canal of the mother, as a result of which the frictional force between the birth canal of the mother and the child to be delivered is significantly reduced. The reduction in frictional force cannot be achieved by application of the composition to the external surfaces of the vaginal tissue.

Finally, the composition according to Van Leuven is also not suitable for being used as a lubricant in human vaginal child birthing. As explained above, the composition requires a pH in the range of from 7.2 to 7.8 in order to ensure long-term stability. On the other hand, a woman's vaginal secretion naturally

exhibits a pH significantly below 7. An alkaline solution as described in Van Leuven is thus unphysiological and can result in both mucous membrane irritations in the mother's vagina and irritations of the child's eyes.

Rejections under 35 USC § 103

Claim 14 is rejected under 35 USC § 103 as being obvious over Van Leuven in view of Levy. The Examiner alleges that Levy teaches a lubricant comprising petroleum, water, grease, synthetic lubricant or solid lubricant and that, therefore, modifying the Van Leuven compounds according to Levy renders obvious claim 14 of the instant invention.

As discussed above and in light of the amendment to claim 12, Van Leuven does not teach all of the elements of the instant invention, and Levy does not provide these missing elements to overcome Van Leuven's deficiencies. Van Leuven disclose a liquid composition which brings about a significant risk of complications for both mother and child due to its aqueous consistency. However, in order to reduce complications during delivery, a lubricant for use in human child birthing must exhibit, inter alia, a high viscosity for preventing an aspiration of the lubricant into the lungs of the fetus and for preventing an infiltration of the lubricant into the motherly blood circuit (amniotic fluid embolism), a high capacity for binding water, a high water resistance, a slightly acidic pH for preventing mucous membrane irritations and for diagnosing amniorexus, as well as transparency for permitting a diagnosis of the condition of the fetus.

The use of a composition in the form of a paste, gel, cream, suppository or foam overcomes the deficiencies encountered with liquid formulations. In particular, it is thus possible to avoid or at least significantly reduce both an aspiration of the lubricant into the lungs of the fetus and an infiltration of the lubricant into the motherly blood circuit in case of an injury of the birth canal.

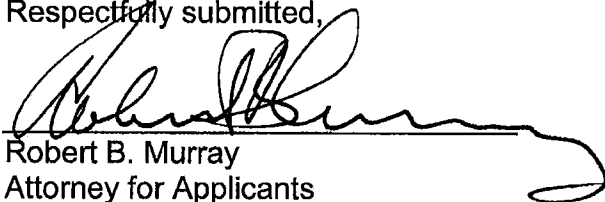
Hence, the use of liquids as lubricants in human child birthing is not at all appropriate and could even be fatal for both mother and child.

Finally, Levy is directed to a process for manufacturing a lubricant containing a superabsorbent polymer. These lubricants are industrial in nature (e.g., motor oil and automatic transmission fluid, para. 17; fire resistance applications, para. 34; metal working, para. 60). A person of ordinary skill in the art in the birth facilitation field would never look to the industrial lubricant field for any problem being addressed. It is improper to base a rejection on non-analogous prior art, and thus Levy is not a proper reference to support an obviousness rejection.

In view of the foregoing, it is submitted that the present application is now in condition for allowance. Reconsideration and allowance of the pending claims are requested. The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

By



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